8EHQ-0102-1347

DuPont Chemical Solutions Enterprise Jackson Laboratory Chambers Works Deep water, NJ 08023 USA



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DuPont Chemical Solutions Enterprise



8EHQ-91-1347

November 7, 2001

Certified Mail-Return Receipt Requested

Document Control Office (7407)
Attention: TSCA Section 8(c)
Room G99 East Tower, Waterside Mall
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460-0001

Contain NO CBI

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Dear 8(e) Coordinator:

8EHQ-0991-1347



Referencing my letter to you of September 6, 2001 on the subject matter, this is to notify you of additional findings that occurred last week. In the 90-Day (13 week) sub-chronic oral (feeding) study initiated last August that is being conducted in rats with the referenced chemical in accordance with OECD Protocol 408, a male rat in the high-dose group was sacrificed for humane reasons in the last week of the study. The in-life phase of the study terminated on November 2, 2001.

Groups of 10 male and 10 female Crl:CD(SD) IGS BR rats per dose group were administered the test compound through the diet. Test concentrations were 0, 10, 50 and 150 mg/kg body weight/day. In-life phase evaluations included clinical observations, detailed physical examinations, sensory reactivity and grip strength, motor activity, body weight changes, food and water consumption and ophthalmic examinations.

The animal that was sacrificed on October 30, 2001 had lost 90.6 grams in weight during the twelfth week of the study and it lost a further 18.5 g in the 24 hours immediately preceding sacrifice. All surviving rats in this dose group (both males and females) progressed well through to the end of the dosing period.

Additionally, preliminary results from the neuro-behavioral screening show a marked decrease in the motor activity times for the female rats in the high dose group (150 mg/kg/day). Low readings are also recorded for the male rat that was sacrificed on October 30 and for another male rat in the same dose group. The response of the other individual animals in this dose group is similar to those of the control group.

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Group mean grip strength was marginally reduced for forelimbs among females in the high dose group, but this appears to be largely due to a low value recorded for a single animal.

Since neuro-behavioral results can be significantly influenced by non-neurological toxic responses, in view of the deaths observed in the high dose group (previously reported to EPA) the effect on motor activity is not necessarily indicative of neurotoxicity. Detailed assessment of these results is presently underway.

EPA is being notified of these findings under TSCA §8(e) because they are believed to be reportable based on guidance provided in the Agency's 1991 TSCA Section 8(e) Reporting Guide.

You may contact me on 856-540-4576 if there are any questions.

Yours truly,

Kavsy D. Dastur

Manager, Product Toxicology & Chemical

Regulations

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By certified mail

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